
APPENDIX A. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K970496

Applicant Information:

MAY - 9 1997

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|-----------------|--|
| Date Prepared: | February 7, 1997. |
| Name: | Heartport, Inc. |
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Device Information:

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|----------------|---------------------------------------|
| Classification | Class II |
| Trade Name: | Heartport™ Maze System: Cryoprobe Set |
| Common Name: | Cryosurgical unit and accessories |
| Product Code: | GEH |

Equivalent Devices:

The Heartport™ Maze System: Cryoprobe Set is substantially equivalent in intended use and/or method of operation to the following predicate devices:

1. Frigitronics® CCS-200 Cardiac Cryosurgical System
2. Spemby Medical - Cardiac Cryounit and associated Cardiac Cryoprobes

Intended Use:

The Heartport™ Maze System: Cryoprobe Set is intended for use in minimally invasive cardiac surgery procedures, including the surgical treatment of cardiac arrhythmias. The cryoprobes are applied to tissue and frozen to cause a block of electrical conduction through tissue by way of an inflammatory response, or cryonecrosis. The Set includes probes of varied tip shapes to optimize access to the treatment site.

510(k) Summary of Safety and Effectiveness (continued)**Comparison To Predicate Devices:**

The Heartport™ Maze System: Cryoprobe Set is equivalent in intended use and operational characteristics to the Frigitronics® Cryoprobes and the Spembly Medical Cardiac Cryoprobes. The Heartport™ Maze System: Cryoprobe Set is specifically designed for introduction and use via a trocar or incision in minimally invasive cardiac surgery procedures.

Non-Clinical Test Results:*Performance*

Heartport™ Maze System: Cryoprobe Set meets the applicable sections of ASTM F 882 - 84 *Standard Performance and Safety Specification for Cryosurgical Medical Instruments*.

Biocompatibility

The materials used to fabricate the Heartport™ Maze System: Cryoprobe Set are similar to the predicate devices. All materials used in the Heartport™ Maze System: Cryoprobe Set have established biocompatibility.

Summary:

Based on the intended use, product information, performance data and biocompatibility information provided in this premarket notification, the Heartport™ Maze System: Cryoprobe Set has been shown to be substantially equivalent to currently marketed predicate devices.